**EXHIBIT C**

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS PHARMA AG, and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., | **Hon. Dennis M. Cavanaugh** |
| Plaintiffs, | **OPINION** |
| v. | Civil Action No. 05-CV-1887 (DMC) |
| TEVA PHARMACEUTICALS USA, INC., | |
| Defendant. | |

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon Defendant Teva Pharmaceuticals USA, Inc.'s (Teva) motion to strike Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Pharma AG, and Novartis International Pharmaceutical Ltd.'s ("collectively Novartis") claims related to Teva's detailed statement and request for exceptional case status. For the reasons set forth below, Teva's motion is **denied.**

## BACKGROUND

The instant case is a patent infringement action arising under the Hatch-Waxman Act, which governs the approval of generic drugs by the U.S. Food and Drug Administration ("FDA"). Novartis is the owner of United States Patent No. 5, 246, 937 ("the 937 Patent"). Complaint at ¶9. Pursuant to the Hatch-Waxman Act, Teva filed an abbreviated new drug

application ("ANDA") seeking FDA approval to commercially manufacture famciclovir tablets. Id. at ¶11. Teva's ANDA application included a certification made pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (the "Paragraph IV Certification") with respect to Novartis' 937 patent. Id. at ¶13. Teva's Paragraph IV Certification stated that the 937 patent is invalid or would not be infringed by Teva's application. Id. On February 22, 2005, as required by the Hatch-Waxman Act, Teva sent Novartis a notice letter, entitled "Detailed Statement", explaining why Teva's proposed generic version of Novartis' tablets will not infringe upon any valid or enforceable claim of Novartis' patents. Id. at ¶15.

On April 8, 2005, after receipt of Teva's Notice letter, Novartis filed a complaint against Teva for infringement on the 937 patent on ground that the notice letter was deficient. Novartis alleges that Teva's manufacture of famciclovir would constitute direct infringement on one or more of the method claims of the 937 patent. Comp. at ¶18. Teva filed an answer to the Complaint on June 3, 2005, asserting counterclaims for invalidity, non-infringement and unenforceability of the 937 patent. Simultaneously, Teva filed the instant motion to strike.

In its moving papers, Teva requests that this Court strike Novartis' allegations in its Complaint that (1) Teva failed to "provide the required detailed statement and legal basis in its notice letter" as required by 21 U.S.C. § 355(j)(2)(B)(ii) of the Drug Price Competition and Patent Restoration Act of 1984 ("the Hutch-Waxman Act") (Complaint ¶20, Prayer for Relief ¶B) and (2) that this is an "exceptional case" entitling Novartis to attorneys fees under 35 U.S.C. § 285 of the patent statute. (Complaint ¶21, Prayer for Relief ¶F). The court will examine each of Teva's requests as to strike in turn.

**DISCUSSION**

***Detailed Statement***

Teva argues that the Federal Circuit's ruling in Minnesota Mining and Manuf. Co. v. Barr Labs., Inc., 289 F.3d 775, 777 (Fed. Cir. 2002) ("3M") bars Novartis from pursuing a cause of action based upon a deficient notice letter, and that this Court is therefore precluded from considering Novartis' allegations of a deficient notice letter. As such, Teva is requesting the Court strike paragraph 20 of Novartis' Complaint and paragraph B of the prayer for relief.

In response, Novartis states that it is not asking the court to enforce the Notice Letter statute or declare the Notice Letter insufficient under the statute, causes of action prohibited under 3M. Rather, Novartis avers that the purpose of its allegation of an incomplete or flawed Notice Letter is to support its claim of willful infringement/ litigation misconduct, appropriate under the Federal Circuit's holding in Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1342 (Fed. Cir. 2000). Furthermore, Novartis asserts that it has not identified any action it wishes the court to take with regard to the Notice Letter, nor any remedy it may be entitled to as a result of any lack of compliance with the notice statute.

In light of the fact that Novartis' allegations regarding the Notice Letter are in the Complaint to support Novartis' request for exceptional case status, the Court does not find it necessary strike Novartis' allegations regarding the insufficiency of the Notice Letter.

***Exceptional Case Status***

Tevat requests that the Court strike those portions of the Complaint that concern Novartis' claim for exceptional case status, on the grounds that the filing of an ANDA cannot support the finding of willful infringement for purposes of awarding attorneys fees under 35 U.S.C. § 285. Teva relies on Glaxo Group Limited v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir.

2004), where the Federal Circuit found that the evidence presented by Glaxo, which consisted mainly of an ANDA filing, did not support a claim for willful infringement for purposes of awarding attorneys fees.

Under 35 U.S.C. § 285, "the [C]ourt in exceptional circumstances may award reasonable attorneys fees to the prevailing party." Furthermore, 35 U.S.C. § 271(e)(4) specifically states that when infringement is based on the filing of an ANDA, "a court may award attorneys fees under Section 285." In Yamanouchi, the Federal Circuit held that a patentee in a ANDA case can recover attorney fees for willful infringement/ litigation misconduct under the appropriate circumstances. 231 F.3d 1339, 1342. Yamanouchi involved a similar pattern of facts as those alleged here: the filing of an ANDA, the Paragraph IV certification, the Notice Letter, and litigation misconduct, and the Federal Circuit found exceptional case status warranted.

Novartis argues that Teva's reliance upon Glaxo is incorrect, and that Yamanouchi controls. This Court agrees. Although Teva is correct in stating that Glaxo stands for the proposition that an ANDA filing, without more, does not constitute willful infringement, it is possible that Novartis may be able to show activity in addition to the ANDA filing to support the issue of wilfulness. As such, under Yamanouchi, Novartis is entitled to proceed with litigation under the current state of the pleadings. If after discovery the evidence is such that Novartis' claim cannot be supported, Novartis may consider voluntarily withdrawing its claim or Teva may renew its application.

In light of the above, Teva's request to strike portions of the Complaint relating to Novartis' request for exceptional case status must be denied.

## CONCLUSION

Based on the foregoing, Teva's motion to strike Novartis' claims related to Teva's detailed statement and request for exceptional case status is **denied**. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: December 30, 2005
Original: Clerk's Office
cc: All Counsel of Record
File